

nesium Sulphate," appearing on the 8-ounce bottle label, were not the common or usual name for Epsom salt. (6) In that the envelopes failed to bear an accurate statement of the quantity of contents since the statement "3 Dram" was not an accurate statement of the quantity of contents of the package. (7) In that the declaration of quantity of contents on the bottles was not prominently placed thereon with such conspicuousness (as compared with other words, statements, and designs in the labeling) as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use, since the statement did not appear upon the principal display panels of the labels.

On June 13, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

557. Misbranding of Velpaus Pills. U. S. v. 4½ Dozen Packages of Velpaus Pills. Default decree of condemnation and destruction. (F. D. C. No. 5106. Sample No. 29500-E.)

This product, in addition to failure to bear adequate directions for use and warning statements, bore false and misleading therapeutic claims.

On July 9, 1941, the United States attorney for the Southern District of Ohio filed a libel against the above-named product at Columbus, Ohio, alleging that it had been shipped on or about June 2, 1941, by F. W. Briggs & Co. from Buffalo, N. Y.; and charging that it was misbranded.

Analysis of a sample of the article showed that it consisted essentially of aloes, ferrous sulfate, myrrh, and starch, together with volatile oils including savin oil, and coated with sugar and chalk.

The article was alleged to be misbranded: (1) In that it failed to bear adequate directions for use since those given on the carton and in the circular were not appropriate for the administration of a laxative. (2) In that the labeling failed to bear adequate warnings against use in those pathological conditions where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, since the warning which was printed on the circular failed to convey the information that this particular article should not be taken when suffering from nausea, abdominal pain, vomiting, or other symptoms of appendicitis and that frequent or continued use might result in dependence upon a laxative. (3) In that the following statements, "Two days before the expected menstruation take one pill before meals and at bedtime. Bathe the feet and lower legs in hot mustard water. Drink freely of hot ginger tea. Cover up and keep warm. This preparation may be dangerous and should be used under medical supervision," were false and misleading since it did not constitute a treatment for delayed menstruation and would not be effective when used under medical supervision. (4) In that the following statements, "In constipation cases we recommend a mild cathartic to keep the bowels open and easy. Exercise in the open air is helpful, keeping the body and feet warm. Not for habitual use. In case of nausea, abdominal pain, or vomiting, avoid the use of all laxatives and cathartics," were false and misleading since they failed to reveal that it was a laxative and they created the impression that some other product should be taken if a laxative action were desired.

On October 10, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

558. Adulteration and misbranding of vitamin B complex tablets. U. S. v. 2,750 Special Formula No. 8558 Tablets and 717 Bottles and 65 Envelopes of Vitamin B Laxative. Default decree of condemnation and destruction. (F. D. C. No. 4873. Sample Nos. 11178-E to 11180-E, incl., 11401-E to 11403-E, incl.)

These tablets represented a portion of a bulk shipment of tablets in 2 drums labeled in part "Special Formula No. 8558," the greater portion of which had been repackaged and relabeled by the consignee after shipment. In addition to failure to bear adequate directions for use and warning statements, the labeling of these tablets bore false and misleading statements regarding their composition and therapeutic efficacy and also failed to bear the common or usual names of their active ingredients.

On June 5, 1941, the United States attorney for the Western District of Texas filed a libel against 2,750 Special Formula No. 8558 Tablets, 737 bottles and 65 envelopes containing a total of 45,521 tablets at San Antonio, Tex., alleging that the article had been introduced in interstate commerce on or about February 1, 1941, at Bristol, Tenn., and that it was then in the possession of the Medical

Specialty Co. at San Antonio, Tex.; and charging that it was adulterated and misbranded.

The article was labeled in part: (Repackaged portion, bottles) "500 [or "100" or "50"] Compressed Tablets 'Vitalax' non habit forming. Vitamin B Laxative from yeast concentrate with Sodium Glyco and Taurocholate. Water soluble vitamin B complex from fresh dehydrated Brewer's yeast Stimulates liver function. Produces abundant flow of bile necessary for normal digestion and proper elimination without the use of habit forming cathartic drugs. Suggested Dose 1 to 3 tablets daily * * * Each Tablet Contains: Sodium Taurocholate 0.0325 Gm. Sodium Glycocholate 0.0325 Gm. Yeast Concentrate 0.026 Gm.": (portion of bottles and drum containing tablets not repackaged) "12 Compressed Tablets 'Vitalax' Each Tablet Contains Sodium Taurocholate 0.015 Gm. Sodium Glycocholate 0.015 Gm. Yeast Concentrate 0.025 Gm. * * * Vitamin B Laxative Concentrate with Bile Salts Compound Water soluble Vitamin B Complex from Fresh Dehydrated Brewer's Yeast"; (envelopes) "5 Compressed Tablets 'Vitalax' Non-Habit Forming For Faulty Elimination Vitamin B Laxative from yeast concentrate with Sodium Glyco and Taurocholate. * * * it tends to tone the digestive tract. Produces abundant flow of bile of physiologically normal composition. Stimulates peristaltic action without the use of habit-forming cathartic drugs. Suggested dosage: 1 to 3 tablets daily."

Analyses of samples of the article showed that it contained phenolphthalein (approximately 1 grain per tablet) together with extracts of yeast and bile.

The article was alleged to be adulterated in that a substance, phenolphthalein, had been substituted in part therefor.

It was alleged to be misbranded: (1) In that its labeling failed to bear adequate directions for use since (in the case of the tablets in original container) the label bore no directions for use, and (in the case of the repackaged tablets) the statement "Suggested dose 1 to 3 tablets daily" was not a suitable or appropriate direction for the use of laxative tablets of its composition. (2) In that the labeling failed to bear adequate warnings against use by children where its use might be dangerous to health; against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, since it failed to bear adequate warnings against the potential danger of establishing dependence upon laxatives to move the bowels; it failed to bear a warning to discontinue its use on the appearance of a skin rash; and, in the case of the repackaged portion, it failed to bear a warning against its use in the presence of abdominal pain, neusea, vomiting, or other symptoms of appendicitis. (3) In that the statements on the labels were false and misleading with respect to its composition, since they did not reveal the material fact that the tablets contained phenolphthalein, a coal-tar laxative drug. (4) (Repackaged portion only) In that the designations, "Vitalax" and "Vitamin B Laxative," on the labels were false and misleading since they gave the impression that the laxative property of the tablets was due to their vitamin or vitamin B content; whereas such laxative property was not due to their vitamin or vitamin B content but to their phenolphthalein content. (5) (Portion repackaged in bottles only except those containing 12 tablets) In that the statements on labels, "Stimulates liver function" and "Produces abundant flow of bile necessary for normal digestion and proper elimination without the use of habit forming cathartic drugs," were false and misleading since it was not efficacious for such purposes and did contain a habit-forming cathartic drug, namely, phenolphthalein. (6) (Portion repackaged in envelopes) In that the statements on the label, "It tends to tone the digestive tract. Produces abundant flow of bile of physiologically normal composition. Stimulates peristaltic action without the use of habit-forming cathartic drugs," were false and misleading since it would not tone the digestive tract, would not produce an abundant flow of bile of physiologically normal composition, and would stimulate peristaltic action because of its content of a habit-forming cathartic drug, phenolphthalein. (7) (Repackaged portion only, except bottles containing 12 tablets) In that the statement "Non Habit Forming" on the labels was false and misleading since its frequent or continued use might result in the establishment of the laxative habit. (8) In that the labeling failed to bear the common or usual name of each of its active ingredients, since it did not mention phenolphthalein, an active ingredient. (9) (Repackaged portion only) In that bile extract was an active ingredient but was not specified on the label by its common or usual name, since neither "Sodium Taurocholate," "Sodium Glycocholate," nor (in the case of the bottles containing 12 tablets) "Bile Salts Compound," is the common or usual name of bile extract.

On August 27, 1941, the Medical Specialty Co., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond to be relabeled under the supervision of the Food and Drug Administration.

559. Misbranding of Cravex. U. S. v. 42 Packages of Cravex. Default decree of condemnation and destruction. (F. D. C. No. 4723. Sample No. 11249-E.)

In addition to failure to bear adequate directions for use in the labeling, this product was misbranded in that the name "Cravex" in the labeling would falsely imply that it constituted an adequate treatment for alcoholism.

On May 8, 1941, the United States attorney for the Southern District of Texas filed a libel against 42 packages of Cravex at Houston, Tex., alleging that it had been shipped on or about February 21, 1941, by Plant Products Co., Inc., from Burbank, Calif.; and charging that it was misbranded.

Analysis of a sample of the article showed that it consisted essentially of calcium and manganese compounds, including phosphates, caffeine, and milk sugar.

The article was alleged to be misbranded (1) in that the labeling did not bear adequate directions for use, since the directions appearing on the package were not adequate for the treatment of alcoholism, a disease for which it was advertised; and (2) in that the labeling was false and misleading since the name "Cravex" was interpreted by advertising to mean treatment for craving for alcohol, and it did not constitute adequate treatment for such condition.

On June 17, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS SEIZED BECAUSE OF CONTAMINATION WITH FILTH

560. Adulteration of bonita livers. U. S. v. 122 Cans of Bonita Livers. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 5417. Sample No. 63538-E.)

Portions of this product were found to be decomposed and putrid.

On August 20, 1941, the United States attorney for the Western District of Washington filed a libel against 122 5-gallon cans of bonita livers at Seattle, Wash., alleging that the article had been shipped by Parke, Davis & Co. from San Francisco, Calif., on or about July 30, 1941; and charging that it was adulterated in that it consisted in whole or in part of a filthy substance.

It also was alleged to be adulterated under the provisions of the law applicable to foods, as reported in F. N. J. No. 2993.

On September 10, 1941, Parke, Davis & Co., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond conditioned that it be brought into compliance with the law under the supervision of the Food and Drug Administration. Subsequently all the cans containing the product were inspected and those found to be unfit were destroyed.

561. Adulteration of crude drugs. U. S. v. 2 Barrels of "Broken Alex Senna Lvs Pumpkin Seed American Wormseed Anise Seed." Default decree of condemnation and destruction. (F. D. C. No. 5673. Sample No. 48086-E.)

This product was contaminated with insect fragments and excreta.

On September 11, 1941, the United States attorney for the Northern District of Georgia filed a libel against 2 barrels of the above-named product at Atlanta, Ga., alleging that the article had been shipped in interstate commerce on or about January 28, 1941, by R. Hillier's Son, Corporation from New York, N. Y.; and charging that it was adulterated in that it consisted in part of a filthy substance.

On October 7, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

562. Adulteration of ginger root. U. S. v. 47 Bags of Ginger. Consent decree of condemnation. Product ordered released under bond to be converted into an inedible product. (F. D. C. No. 6356. Sample No. 67714-E.)

Examination showed that this product contained worm holes and further evidence of insect infestation.

On December 4, 1941, the United States attorney for the Western District of Tennessee filed a libel against 47 bags containing 5,229 pounds of ginger at Memphis, Tenn., alleging that the article had been shipped in interstate commerce on or about September 6, 1940, by J. R. Watkins Co. from Newark, N. J.; and charging that it was adulterated in that it consisted in whole or in part of a filthy, putrid, or decomposed substance.